K032945

MAY 25 2004

Stryker
INSTRUMENTS

4100 East Milham Avenue
Kalamazoo, MI 49001
Phone (269) 323-7700
(800) 253 3210

510(k) Summary

Trade Name: Stryker Spineplex™ Radiopaque Bone Cement

Common Name: PMMA bone cement

Classification: Bone Cement, 888.3027

Equivalent to: Stryker Simplex® P

Device Description: Stryker Spineplex™ Radiopaque Bone Cement is a PMMA bone cement made of the same chemical components as Stryker Simplex® P.

Intended Use: Spineplex™ Radiopaque Bone cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Technological Comparison: Stryker Spineplex™ Radiopaque Bone Cement is made of the exact components a Simplex™ P. The ratio of the ingredients has been modified to increase the working time and enhance visualization of the cement to meet customer needs in the fixation of vertebral compression fractures.

Submitted by: Dannielle C. Wheeler
Sr. Regulatory Affairs Representative
Stryker Instruments

Dannielle C Wheeler 5/11/04
Signature Date

Date Submitted: Sept. 19, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2004

Ms. Dannielle Wheeler
Senior Regulatory Affairs Representative
Stryker Corporation
Instrument Division
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K032945
Trade/Device Name: Spineplex™ Radiopaque Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: PMMA Bone Cement
Regulatory Class: II
Product Codes: LOD, NDN
Dated: February 27, 2004
Received: March 1, 2004

Dear Ms. Wheeler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, PhD, MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032945

Device Name: Spineplex™ Radiopaque Bone Cement

Indications for Use:

Spineplex™ Radiopaque Bone cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K032945